

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BAXTER HEALTHCARE CORPORATION,)	
BAXTER INTERNATIONAL INC., and)	
BAXTER HEALTHCARE SA,)	Civil Action No. 09-582-GMS
)	
Plaintiffs,)	
)	
v.)	
)	
MINRAD, INC.,)	
MINRAD INTERNATIONAL, INC.,)	
PIRAMAL HEALTHCARE LIMITED, and)	
PIRAMAL HEALTHCARE, INC.,)	
)	
Defendants.)	
)	

**PLAINTIFFS' REPLY TO COUNTERCLAIMS OF DEFENDANT
MINRAD, INC.**

Plaintiffs Baxter Healthcare Corporation ("Baxter HC"), Baxter International Inc. ("Baxter II") and Baxter Healthcare SA ("Baxter HSA"), (collectively, "Plaintiffs"), by and through their undersigned counsel, hereby reply to the counterclaims ("Counterclaims") set forth in the Answer, Affirmative Defenses and Counterclaims of Defendant Minrad, Inc. as follows:

1. Plaintiffs lack information or knowledge sufficient to form a belief as to the truth of the allegations set forth in paragraph 1 of the Counterclaims and therefore leave Defendant Minrad, Inc. ("Minrad") to its proofs.
2. Plaintiffs admit the allegations of paragraph 2 of the Counterclaims.
3. Plaintiffs admit the allegations of paragraph 3 of the Counterclaims.
4. Plaintiffs admit the allegations of paragraph 4 of the Counterclaims.
5. Plaintiffs admit that this Court has subject matter jurisdiction over Minrad's Counterclaim, Count I, for Declaratory Judgment. Plaintiffs deny that this Court has subject matter jurisdiction over Minrad's Counterclaim, Count II, Breach of Contract, or subject matter

jurisdiction over Minrad's Counterclaim, Count III, Unjust Enrichment. Plaintiffs deny the remaining allegations set forth in paragraph 5 of the Counterclaims.

6. Plaintiffs admit the allegations of paragraph 6 of the Counterclaims.

7. Plaintiffs admit the allegations of paragraph 7 of the Counterclaims.

8. Plaintiffs admit that this Court has personal jurisdiction over Baxter Healthcare SA ("Baxter HSA") for Minrad's Counterclaim, Count I, for Declaratory Judgment. Plaintiffs deny that this Court has personal jurisdiction over Baxter HSA as to Minrad's Counterclaim, Count II, Breach of Contract, or personal jurisdiction over Baxter HSA as to Minrad's Counterclaim, Count III, Unjust Enrichment. Plaintiffs deny the remaining allegations set forth in paragraph 8 of the Counterclaims.

9. Plaintiffs admit that venue is proper in this district under 28 U.S.C. § 1400 as to Minrad's Counterclaim, Count I, Declaratory Judgment. Plaintiffs admit that venue is proper in this district as to Baxter HC and Baxter II with regard to Minrad's Counterclaim, Count II, Breach of Contract, and Minrad's Counterclaim, Count III, Unjust Enrichment. Plaintiffs deny that venue is proper in this district as to Baxter HSA with regard to Minrad's Counterclaim, Count II, Breach of Contract, or as to Minrad's Counterclaim, Count III, Unjust Enrichment. Plaintiffs deny the remaining allegations set forth in paragraph 9 of the Counterclaims.

10. Plaintiffs admit that Baxter HSA manufactures desflurane, a general inhalation anesthetic. Plaintiffs admit that Baxter Healthcare Corporation ("Baxter HC") sells and distributes desflurane under the trade name "Suprane®." Plaintiffs deny the remaining allegations set forth in paragraph 10 of the Counterclaims.

11. Plaintiffs admit that U.S. Patent No. 4,762,856 ("the '856 patent"), entitled "Anaesthetic composition and method of using same," is no longer in force or effect. Plaintiffs deny the remaining allegations set forth in paragraph 11 of the Counterclaims.

12. Plaintiffs admit that Baxter HC was provided with notice that ANDA No. 90-363 was filed seeking approval to market a generic desflurane inhalant anesthetic product. Plaintiffs lack information or knowledge sufficient to form a belief as to the truth of the remaining allegations set forth in paragraph 12 of the Counterclaims and therefore leave Minrad to its proofs.

13. Plaintiffs admit that Baxter HC has listed U.S. Patent No. 5,617,906 ("the '906 patent") in the list of Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book"), maintained by the Food and Drug Administration ("FDA"), as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" Suprane®. *See* 21 U.S.C. § 505(b)(1). Plaintiffs deny the remaining allegations of paragraph 13 of the Counterclaims.

14. Plaintiffs admit that Plaintiffs received on or about December 12, 2008, a letter from Minrad dated December 11, 2008, purporting to be a notice of Minrad's abbreviated new drug application ("ANDA") and "Paragraph IV" certification(s) required by 21 U.S.C. § 355(j)(2)(B)(i)-(ii). Plaintiffs deny the remaining allegations of paragraph 14 of the Counterclaims.

15. Plaintiffs admit that Minrad supplied a document entitled "Abbreviated New Drug Application No. 90-363 Offer of Confidential Access Pursuant to 21 U.S.C. § 355(J)(5)(C)(i)(III)" ("the Offer of Confidential Access"), which was executed on behalf of

Baxter HC on January 5, 2009. Plaintiffs admit that the copy of the Offer of Confidential Access attached to the Answer, Affirmative Defenses and Counterclaims of Defendant Minrad, Inc., appears to be a true and accurate copy of the executed Offer of Confidential Access. Plaintiffs deny the remaining allegations of paragraph 15 of the Counterclaims.

16. Plaintiffs admit that Plaintiffs filed Civil Action No. 09-054 in this Court, on or about January 23, 2009, alleging infringement of the '906 patent by Minrad, Inc. Plaintiffs deny the remaining allegations of paragraph 16 of the Counterclaims.

17. Plaintiffs admit that Baxter HC was given notice that Minrad filed an amendment to ANDA No. 90-363 relating to changes to the bottle closure design. Plaintiffs lack information or knowledge sufficient to form a belief as to the truth of the remaining allegations set forth in paragraph 17 of the Counterclaims and therefore leave Minrad to its proofs.

18. Plaintiffs admit that on or about June 23, 2009, Susan Lichtenstein, General Counsel, Baxter HC, received a letter from Minrad, which purported to be a "Notice of Paragraph IV Certification Filing" relating to amendment of Minrad's ANDA No. 90-363. Plaintiffs deny the remaining allegations set forth in paragraph 18 of the Counterclaims.

19. Plaintiffs admit that on or about June 23, 2009, Susan Lichtenstein, General Counsel, Baxter HC, received a letter from Minrad that was not marked "confidential," and copies were sent by Minrad to, among others, Raul Trillo and Gerald Mosely of Baxter HC. Plaintiffs admit that the June 23, 2009 letter contained an unredacted version of what purports to be an "Amendment June 23, 2009" relating to Minrad's ANDA Application No. 90-363. Plaintiffs deny the remaining allegations set forth in paragraph 19 of the Counterclaims.

20. Plaintiffs deny the allegations set forth in paragraph 20 of the Counterclaims.

21. Plaintiffs admit that Baxter HC, through its outside counsel, has informed Minrad's outside counsel, in a letter dated August 6, 2009, that Minrad's decision to send its June 23 Notice of Paragraph IV Certification Filing with portions of the ANDA to three persons at Baxter HC who were never designated to receive confidential Minrad information pursuant to the January 5, 2009 Offer of Confidential Access serves to confirm that the June 23 Notice and related documentation is not covered by the June 5, 2009 Offer of Confidential Access. Plaintiffs admit that Baxter HC, through its outside counsel, has informed Minrad's outside counsel, in a letter dated August 6, 2009, that the January 5, 2009 Offer of Confidential Access is limited on its face to two, and only two, items: (1) a redacted copy of ANDA No. 90-363 that was provided by Minrad on January 5, 2009, and (2) a limited number of prototypes of a Minrad closure system that were provided by Minrad on January 6, 2009, and that Baxter HC's obligations under the January 5, 2009 Offer of Confidential Access extended only to the two above-identified items. Plaintiffs admit that, unlike the redacted copy of ANDA 90-363 supplied on January 5, 2009 pursuant to the January 5, 2009 Offer of Confidential Access and marked "CONFIDENTIAL" in each page in large capital letters, the ANDA documents supplied by Minrad on June 23, 2009 were not redacted. Plaintiffs deny the remaining allegations set forth in paragraph 21 of the Counterclaims.

22. Plaintiffs admit that Minrad, through its outside counsel, contended for the first time in a letter dated July 31, 2009, that the documents provided in the letter of June 23, 2009 were subject to the restrictions set forth in the January 5, 2009 Offer of Confidential Access. Plaintiffs admit that Minrad, through its outside counsel, in a letter dated August 4, 2009, requested that Baxter HC "identify each and every person to whom it has given access to Minrad's June 23, 2009 Notice of Paragraph IV Certification Filing." Plaintiffs admit that Baxter

HC, through its outside counsel, in a letter dated August 6, 2009, informed Minrad, through its outside counsel, that "in the spirit of cooperation and to put this matter to rest, Baxter is willing to request that any persons who have received or reviewed a copy of Minrad's June 23 Notice of Paragraph IV Certification filing or [Minrad's counsel's] letter of July 31, 2009, except outside counsel, Ms. Laura DeMoor and Ms. Sarah Padgitt, destroy any copies of these documents. We trust that this will put an end to the debate on this matter. If you agree, Baxter will promptly request the destruction of the documents." Plaintiffs admit that Minrad, through its outside counsel, in a letter dated August 10, 2009 requested that Baxter HC's outside counsel "please instruct Baxter not to destroy, but rather to gather and preserve solely in the possession of its outside counsel, any and all copies of the materials that Minrad provided with its June 23, 2009 Notice of Paragraph IV Certification Filing, as well as all documents that refer or relate to those materials and/or any information contained therein (including any and all such documents that are in electronic format, which are to be preserved in their native format)." Plaintiffs admit that Baxter HC, through its outside counsel, informed Minrad, through its outside counsel, in a letter dated August 12, 2009, that "we have instructed all persons who may have received the June 23 Notice or related documents to refrain from any distribution of those documents and to maintain and preserve all copies of those documents in the manner that they have been requested to maintain and preserve all documents potentially relevant to the on-going litigation." Plaintiffs admit that Baxter HC through its outside counsel, informed Minrad, through its outside counsel, in a letter dated August 26, 2009, that Baxter "has instructed all persons who may have received the June 23 Notice or related documents, other than outside counsel, Ms. Laura DeMoor and Ms. Sarah Padgitt, to make no further use of the information contained Minrad's June 23 Notice or related documents and have instructed all persons who may have received the June 23 notice or

related documents to make no further disclosure of the information. We trust that this puts this matter to rest." Plaintiffs deny the remaining allegations set forth in paragraph 22 of the Counterclaims.

23. Plaintiffs admit that Baxter HC, through its outside counsel, informed Minrad, through its outside counsel, in a letter dated August 12, 2009, that "we have instructed all persons who may have received the June 23 Notice or related documents to refrain from any distribution of those documents and to maintain and preserve all copies of those documents in the manner that they have been requested to maintain and preserve all documents potentially relevant to the on-going litigation." Plaintiffs deny the remaining allegations set forth in paragraph 23 of the Counterclaims.

24. Plaintiffs admit that Baxter HC, through its outside counsel, informed Minrad, through its outside counsel, in a letter dated August 12, 2009, that "we have instructed all persons who may have received the June 23 Notice or related documents to refrain from any distribution of those documents and to maintain and preserve all copies of those documents in the manner that they have been requested to maintain and preserve all documents potentially relevant to the on-going litigation." Plaintiffs deny the remaining allegations set forth in paragraph 24 of the Counterclaims.

25. Plaintiffs admit that Baxter HC through its outside counsel, informed Minrad, through its outside counsel, in a letter dated August 26, 2009, that Baxter "has instructed all persons who may have received the June 23 Notice or related documents, other than outside counsel, Ms. Laura DeMoor and Ms. Sarah Padgitt, to make no further use of the information contained Minrad's June 23 Notice or related documents and have instructed all persons who may have received the June 23 notice or related documents to make no further disclosure of the

information. We trust that this puts this matter to rest." Plaintiffs admit that Minrad, through its outside counsel, in a letter dated August 21, 2009, informed Baxter HC that "we accept and appreciate your confirmation that Baxter will preserve all documents that comprise, refer or relate to Minrad's June 23 submission and related materials and that those materials will not be further disseminated." Plaintiffs deny the remaining allegations set forth in paragraph 25 of the Counterclaims.

26. Plaintiffs admit that Baxter HC through its outside counsel, informed Minrad, through its outside counsel, in a letter dated August 12, 2009, that "The current situation is akin to a party producing information without properly designating it as confidential at the time of production in the course of litigation and then providing written notice that information already so produced should be treated as confidential under a protective order. As you know, the draft protective order that the parties have been negotiating in Case. No. 09-054 (GMS) does not require the receiving party in such a situation to take any of the steps that Minrad is now demanding. In fact, the draft protective order requires the receiving party to not retain copies of incorrectly designated materials and to 'undertake a best effort to correct any disclosure of such information contrary to the redesignation.' The draft protective order states that prior to receipt of notice regarding an allegedly incorrect confidentiality designation, disclosure to persons not authorized to receive confidential or highly confidential information 'shall not be deemed a violation' of the protective order. The draft protective order does not require the receiving party to go through the effort of collecting and maintaining every copy of the allegedly incorrectly designated document and it does not require disclosure of the identify of every person who was given access to the document. The parties have already agreed to this provision in the draft

protective order, and Baxter would not agree to a more stringent requirement in this situation."

Plaintiffs deny the remaining allegations set forth in paragraph 26 of the Counterclaims.

Reply to COUNT I
Declaratory Judgment

27. Plaintiffs incorporate by reference and reallege paragraphs 1 through 26 above as if set forth in full herein.

28. Plaintiffs deny the allegations set forth in paragraph 28 of the Counterclaims.

29. Plaintiffs deny the allegations set forth in paragraph 29 of the Counterclaims.

30. Plaintiffs deny the allegations set forth in paragraph 30 of the Counterclaims.

Reply to PRAYER FOR RELIEF

Plaintiffs deny that Minrad is entitled to any of the relief they seek in Count I of the Counterclaims. Plaintiffs request that the Court enter an order dismissing Count I of the Counterclaims with prejudice and granting Plaintiffs such other relief as it deems appropriate.

Reply to COUNT II
Breach of Contract

31. Plaintiffs incorporate by reference and reallege paragraphs 1 through 30 above as if set forth in full herein.

32. Plaintiffs deny the allegations set forth in paragraph 32 of the Counterclaims.

33. Plaintiffs deny the allegations set forth in paragraph 33 of the Counterclaims.

Reply to PRAYER FOR RELIEF

Plaintiffs deny that Minrad is entitled to any of the relief they seek in Count II of the Counterclaims. Plaintiffs request that the Court enter an order dismissing Count II of the Counterclaims with prejudice and granting Plaintiffs such other relief as it deems appropriate.

Reply to COUNT III
Unjust Enrichment

34. Plaintiffs incorporate by reference and reallege paragraphs 1 through 33 above as if set forth in full herein.

35. Plaintiffs deny that paragraph 35 sets forth a proper statement of the law relating to allegations of unjust enrichment. Plaintiffs deny the remaining allegations set forth in paragraph 35 of the Counterclaims.

36. Plaintiffs deny the allegations set forth in paragraph 36 of the Counterclaims.

37. Plaintiffs deny the allegations set forth in paragraph 37 of the Counterclaims.

38. Plaintiffs deny the allegations set forth in paragraph 38 of the Counterclaims.

Reply to PRAYER FOR RELIEF

Plaintiffs deny that Minrad is entitled to any of the relief they seek in Count III of the Counterclaims. Plaintiffs request that the Court enter an order dismissing Count III of the Counterclaims with prejudice and granting Plaintiffs such other relief as it deems appropriate.

AFFIRMATIVE DEFENSES TO THE COUNTERCLAIMS

Plaintiffs state the following affirmative defenses to the Counterclaims:

FIRST AFFIRMATIVE DEFENSE - WAIVER

1. Minrad has waived any right of recovery for alleged breach of contract under Count II of the Counterclaims. The January 5, 2009 Offer of Access expressly states that access will be restricted to specific persons identified to Minrad. By letter dated January 5, 2009, from Dr. Curtiss Mancuso, Director of Regulatory Affairs, Minrad, to Mr. Gerald Mosely, General Manager, Anesthesia, Baxter HC, Dr. Mancuso includes information "per the Confidential Access Agreement," i.e., the January 5, 2009 Offer of Confidential Access. Dr. Mancuso expressly acknowledges Minrad's understanding that information under the January 5, 2009

Offer of Confidential Access should not be sent to Ms. Susan Lichtenstein or to Mr. Raul Trillo at Baxter HC. Minrad's unilateral decision to send the documents on June 23, 2009 to Ms. Lichtenstein and to Mr. Trillo, after expressly acknowledging that neither of those Baxter HC employees were authorized to receive confidential information under the January 5, 2009 Offer of Confidential Access, confirms that (1) any confidentiality obligation that existed at the time was expressly waived, relating to the documents sent on June 23, 2009 by Minrad to Baxter HC, and (2) no breach of any contract, express or implied, can occur based upon any actions taken by employees of Baxter HC based upon receipt of the documents sent on June 23, 2009 by Minrad to Baxter HC.

2. Minrad has waived any right of recovery for alleged breach of contract under Count II of the Counterclaims. The January 5, 2009 Offer of Confidential Access, Section B(2), expressly states that the copy of the ANDA will be "redacted to remove information of no relevance to any issue of patent infringement, and to protect certain trade secrets." Minrad's failure to redact any information from the documents sent by Minrad to Baxter HC on or about June 23, 2009, constitutes an admission that no trade secret, or confidential, information was provided therein, and that (1) any confidentiality obligation that existed at the time was expressly waived, relating to the documents sent on June 23, 2009 by Minrad to Baxter HC, and (2) no damage claim can be sustained by Minrad relating to any actions taken by employees of Baxter HC relating to receipt of nonconfidential information.

3. Minrad has waived any right of recovery for alleged breach of contract under Count II of the Counterclaims. The documents supplied by Minrad on June 23, 2009 were knowingly sent by Minrad to three individuals who were not designees under the January 5, 2009

Offer of Confidential Access, and/or were not subject to the requirements of the January 5, 2009 Offer of Confidential Access.

4. Minrad has waived any right of recovery under Count II or Count III of the Counterclaims based upon its express agreement to provisions relating to the treatment of alleged confidential information in the on-going litigation between the parties. Baxter HC through its outside counsel, informed Minrad, through its outside counsel, in a letter dated August 12, 2009, that "The current situation is akin to a party producing information without properly designating it as confidential at the time of production in the course of litigation and then providing written notice that information already so produced should be treated as confidential under a protective order. As you know, the draft protective order that the parties have been negotiating in Case. No. 09-054 (GMS) does not require the receiving party in such a situation to take any of the steps that Minrad is now demanding. In fact, the draft protective order requires the receiving party to not retain copies of incorrectly designated materials and to 'undertake a best effort to correct any disclosure of such information contrary to the redesignation.' The draft protective order states that prior to receipt of notice regarding an allegedly incorrect confidentiality designation, disclosure to persons not authorized to receive confidential or highly confidential information 'shall not be deemed a violation' of the protective order. The draft protective order does not require the receiving party to go through the effort of collecting and maintaining every copy of the allegedly incorrectly designated document and it does not require disclosure of the identify of every person who was given access to the document. The parties have already agreed to this provision in the draft protective order, and Baxter would not agree to a more stringent requirement in this situation." Minrad's agreement to the provisions of the draft protective order constitutes a waiver of any further recovery or other relief.

5. Minrad waived any right of recovery under either Count II or Count III of the Counterclaims as a result of the actions of Baxter HC, including the assurances provided by Baxter HC on or about August 12, 2009 and August 26, 2009, and Minrad's confirmation of those assurances on August 21, 2009. Baxter HC, through its outside counsel, informed Minrad, through its outside counsel, in a letter dated August 12, 2009, that "we have instructed all persons who may have received the June 23 Notice or related documents to refrain from any distribution of those documents and to maintain and preserve all copies of those documents in the manner that they have been requested to maintain and preserve all documents potentially relevant to the on-going litigation." Baxter HC through its outside counsel, informed Minrad, through its outside counsel, in a letter dated August 26, 2009, that Baxter "has instructed all persons who may have received the June 23 Notice or related documents, other than outside counsel, Ms. Laura DeMoor and Ms. Sarah Padgitt, to make no further use of the information contained Minrad's June 23 Notice or related documents and have instructed all persons who may have received the June 23 notice or related documents to make no further disclosure of the information. We trust that this puts this matter to rest." Minrad, through its outside counsel, in a letter dated August 21, 2009, informed Baxter HC that "we accept and appreciate your confirmation that Baxter will preserve all documents that comprise, refer or relate to Minrad's June 23 submission and related materials and that those materials will not be further disseminated."

SECOND AFFIRMATIVE DEFENSE - FULL PERFORMANCE

6. Plaintiffs, individually and collectively, fully satisfied all obligations, to the extent any obligations exist or existed, under the January 5, 2009 Offer of Confidential Access. Minrad

has no right of any recovery under the January 5, 2009 Offer of Confidential Access under Count II or Count III of the Counterclaims.

7. Plaintiffs, individually and collectively, fully satisfied all obligations, to the extent any obligations exist or existed, with regard to the documents sent by Minrad to Baxter HC on or about June 23, 2009. Minrad has no right of any recovery with regard to the documents sent by Minrad to Baxter HC on or about June 23, 2009 under Count II or Count III of the Counterclaims.

THIRD AFFIRMATIVE DEFENSE - ACCORD AND SATISFACTION

8. Any claim of Minrad, under either Count II or Count III of the Counterclaims, was fully satisfied by the actions of Baxter HC, including the assurances provided by Baxter HC on or about August 12, 2009 and August 26, 2009, and Minrad's confirmation of those assurances on August 21, 2009. Baxter HC, through its outside counsel, informed Minrad, through its outside counsel, in a letter dated August 12, 2009, that "we have instructed all persons who may have received the June 23 Notice or related documents to refrain from any distribution of those documents and to maintain and preserve all copies of those documents in the manner that they have been requested to maintain and preserve all documents potentially relevant to the on-going litigation." Baxter HC through its outside counsel, informed Minrad, through its outside counsel, in a letter dated August 26, 2009, that Baxter "has instructed all persons who may have received the June 23 Notice or related documents, other than outside counsel, Ms. Laura DeMoor and Ms. Sarah Padgitt, to make no further use of the information contained Minrad's June 23 Notice or related documents and have instructed all persons who may have received the June 23 notice or related documents to make no further disclosure of the information. We trust that this puts this matter to rest." Minrad, through its outside counsel, in a

letter dated August 21, 2009, informed Baxter HC that "we accept and appreciate your confirmation that Baxter will preserve all documents that comprise, refer or relate to Minrad's June 23 submission and related materials and that those materials will not be further disseminated."

FOURTH AFFIRMATIVE DEFENSE - NO AUTOMATIC RENEWAL CLAUSE

9. The January 5, 2009 Offer of Confidential Access does not contain any provision for automatic renewal. The January 5, 2009 Offer of Confidential Access is limited on its face to two, and only two, items: (1) a redacted copy of ANDA No. 90-363 that was provided by Minrad on January 5, 2009, and (2) a limited number of prototypes of a Minrad closure system that were provided by Minrad on January 6, 2009. Baxter HC's obligations under the January 5, 2009 Offer of Confidential Access extended only to the two above-identified items. Minrad provided the above-identified items to Baxter HC on or about January 5, 2009 and January 6, 2009. Any obligations of Baxter HC relating to those documents and prototypes supplied on January 5 and 6, 2009, is subject to the provisions of the January 5, 2009 Offer of Confidential Access. However, the January 5, 2009 Offer of Confidential Access does not have an automatic renewal provision. Without the express agreement of the parties to renew the January 5, 2009 Offer of Confidential Access, and apply it to further activities, the absence of an automatic renewal provision means that the January 5, 2009 Offer of Confidential Access does not apply to any activities or actions of the parties unrelated to the specific documents and prototypes provided on January 5 and 6, 2009.

FIFTH AFFIRMATIVE DEFENSE - PUBLIC POLICY AND STATUTORY LIMITATIONS

10. The January 5, 2009 Offer of Confidential Access is void on public policy grounds with regard to Minrad's attempted enforcement as to documents not specifically

identified in the January 5, 2009 Offer of Confidential Access. Minrad's attempted enforcement implies that the requirements of January 5, 2009 Offer of Confidential Access extend in perpetuity with regard to the actions of the parties. Minrad's attempted enforcement is void as contrary to the spirit of the statutory section relating to offers of confidential access, 21 U.S.C. 355(j)(5)(C)(i)(III).

SIXTH AFFIRMATIVE DEFENSE - FAILURE TO STATE A CLAIM

11. Plaintiffs incorporate by reference and reallege paragraphs 1 through 10 of these Affirmative Defenses as if set forth in full herein. Count II of the Counterclaims fails to state a claim upon which relief can be granted.

12. Plaintiffs incorporate by reference and reallege paragraphs 1 through 10 of these Affirmative Defenses as if set forth in full herein. Count III of the Counterclaims fails to state a claim upon which relief can be granted.

PRAYER FOR RELIEF

WHEREFORE, in addition to the relief requested in it Complaint, Plaintiffs respectfully request that the Court dismiss Minrad's Counterclaims with prejudice, and award such other relief in favor of Plaintiffs that it deems just and proper.

POTTER ANDERSON & CORROON LLP

OF COUNSEL:

David T. Pritikin
Hugh A. Abrams
Stephanie P. Koh
Robert D. Leighton
Sidley Austin LLP
One South Dearborn
Chicago, IL 60603
(312) 853 -7000

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939027

By: /s/ Philip A. Rovner
Philip A. Rovner (#3215)
Hercules Plaza
P.O. Box 951
Wilmington, DE 19899-0951
(302) 984-6000
E-mail: provner@potteranderson.com

*Attorneys for Plaintiffs
Baxter Healthcare Corporation,
Baxter International Inc. and
Baxter Healthcare SA*

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

CERTIFICATE OF SERVICE

I, Philip A. Rovner, hereby certify that, on October 23, 2009, the within document was electronically filed with the Clerk of the Court using CM-ECF which will send notification of such filing to the following; that the document was served on the following counsel as indicated; and the document is available for viewing and downloading from CM-ECF:

BY HAND DELIVERY AND E-MAIL

J. Cory Falgowski, Esq.
Kathleen A. Murphy, Esq.
Reed Smith LLP
1201 Market Street, Suite 1500
Wilmington, DE 19801
jfalgowski@reedsmith.com
kmurphy@reedsmith.com

I hereby certify that on October 23, 2009 I have sent by E-mail the foregoing document to the following non-registered participants:

Tracy Zurzolo Quinn, Esq.
Carl H. Pierce, Esq.
Nanda P.B.A. Kumar, Esq.
Reed Smith LLP
One Liberty Place
1650 Market Street
Philadelphia, PA 19103
tquinn@reedsmith.com
cpierce@reedsmith.com
nkumar@reedsmith.com

/s/ Philip A. Rovner
Philip A. Rovner (#3215)
Potter Anderson & Corroon LLP
Hercules Plaza
P. O. Box 951
Wilmington, DE 19899
(302) 984-6000
provner@potteranderson.com